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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,590	05/26/2005	Shojiro Matsuda	10873.1686USWO	9228

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EXAMINER	
CHRISS, JENNIFER A	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
01/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,590	MATSUDA ET AL.	
	Examiner	Art Unit	
	JENNIFER A. CHRISS	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4 – 5, 11 – 28 and 30 - 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4 – 5, 11 – 28 and 30 - 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's Amendments and Accompanying Remarks filed on January 8, 2009 has been entered and carefully considered. Claim 1 is amended, claims 2 – 3, 6 – 10 and 29 are cancelled and claims 1, 4 – 5, 11 – 28 and 30 – 32 are pending. In view of Applicant's amendments and remarks, the Examiner withdraws all previously set forth rejections. The invention as currently claimed is not found to be patentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 1 – 5, 11 – 15, 25 – 26, 28 and 30 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Harvey et al. (US 5,447,940).

Browning is directed to a surgical implant (Title).

As to claims 1, 4 and 30 - 31, Browning teaches a mesh that is coated or encapsulated with an absorbable coating (page 12, lines 7 – 11). Browning teaches that

the absorbable material may comprise a soluble hydrogel such as gelatin (page 13, lines 6 – 8). Browning teaches that the mesh comprises bicomponent fibers comprising a nonabsorbable core and a shorter lasting absorbable surface material such as polylactic acid or polyglycolic acid (page 14, lines 28 - 31). The mesh can comprise a warp knit diamond or hexagon net (page 9, lines 11 - 14) where strand spacing is between 1 - 10 mm (page 7, lines 18 - 20), which is equated to Applicant's "vertical length" and "horizontal length".

As to claim 5, the Figures show that the surgical implant can be in sheet form.

As to claim 11, Browning teaches applying a heat treatment to the warp mesh knit to reduce fraying of the filaments (page 37, lines 1 – 6).

As to claim 12, Browning teaches that the warp knit mesh has a density of less than 50 gsm (page 8, lines 1 – 12), which significantly overlaps with Applicant's claimed range

As to claim 13, Browning teaches that the mesh comprises strands that are approximately 150 - 600 microns in diameters (page 34, lines 12 - 15), therefore, the mesh will be at least 150 - 600 microns in thickness.

As to claim 15, Browning teaches that the mesh comprises bicomponent fibers comprising a nonabsorbable core and a shorter lasting absorbable surface material such as polylactic acid or polyglycolic acid (page 14, lines 28 - 31).

As to claim 25, Browning teaches that the surgical implant is capable of being absorbed by the body in a period less than 48 hours (page 15, lines 6 - 9).

As to claim 26, Browning teaches that the absorbable coating may have a

thickness around 1 – 2 mm (1000 – 2000 micrometers) (page 38, lines 4 - 14).

As to claim 28, Browning teaches the claimed invention above. It should be noted that the recitation of "antiadhesive material" is not given patentable weight at this time since the prior art meets the structural and/or chemical limitations set forth and there is nothing on record to evidence that the prior art product could not function in the desired capacity or that there is some additional implied structure associated with the term. The burden is shifted upon the Applicant to evidence the contrary.

Browning teaches the claimed invention above but fail to teach that the reinforcing material is disposed on at least one film surface of the gelatin film so that part or an entirety of the reinforcing material is inside the gelatin film and the reinforcing material and the gelatin film are integrated due to gelling of gelatin that has infiltrated partially or entirely in an internal part of the reinforcing material as required by claims 1 and 4.

Harvey et al. is directed to an absorbable composite material for use in the treatment of periodontal disease (Title). Harvey et al. teach a composite material comprising a collagen matrix reinforced with a layer of bioabsorbable polymer (column 3, lines 43 – 50). Harvey et al. teach that the collagen matrix can comprise soluble collagen such as gelatin (column 3, lines 55 – 63) and the layer of bioabsorbable polymer can comprise a mesh of woven, non-woven or knitted fibers made from copolymers of lactic acid and glycolic acid or oxidized regenerated cellulose (column 3, lines 45 – 55). The composite is made by pouring the homogenized collagen slurry

over the reinforcing layer, which has been laid out in a flat-bottomed tray. Once the reinforcing layer is covered with the slurry, the water is removed by air-drying or freeze-drying to leave a sheet of composite material (column 5, lines 1 - 5). The Examiner submits that since the matrix is reinforced with the layer of bioabsorbable polymer that the "reinforcing material and the gelatin film are integrated due to gelation of gelatin that has intruded entirely in an internal part of the reinforcing material" as required by Applicant. Harvey notes that the composition is easy to handle, can be cut into any desired shape, soft, conformable and comfortable while maintaining good structural integrity (column 6, lines 59 – 69).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to fully integrate the knit layer as suggested by Harvey et al. into the absorbable coating of Browning motivated by the desire to create an absorbable composite that is easy to handle, can be cut into any desired shape, soft, conformable and comfortable while maintaining good structural integrity

Browning in view of Harvey teach the claimed invention but fail to disclose that the warp knitted fabric comprises a multifilament yarn having a thickness of 30 – 200 denier. It should be noted that the linear density is a result effective variable. Browning indicates that the filaments of the mesh have a diameter of 0.02 to 0.15 mm which is directly related to denier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the knitted mesh of Browning in view of Harvey with a yarn denier ranging from 30 to 200 since it has been held that discovering

an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the yarn denier of Browning in view of Harvey based on the desired strength and flexibility of the surgical implant.

Browning in view of Harvey teach the claimed invention above but fails to teach that the yarn threading tension is in a range of 0.3 - 200 N as required by claim 14 and neither rupture nor exposure of the reinforcing material occurs when the tension is less than 1 N as required by claim 32. It is reasonable to presume that the above properties are inherent to Browning in view of Harvey. Support for said presumption is found in the use of like materials (i.e. a warp knitted mesh having diamond or hexagonal shaped pores made of a biodegradable polymer having the same unit of stitches coated with a gelatin) which would result in the claimed properties. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would obviously have been present once the Browning in view of Harvey product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Harvey et al. (US 5,447,940), as applied above, and further in view of Jurgens (US 5854381).

Browning in view of Harvey teach the claimed invention above but fail to teach the use of 85:15 – 40:60 lactide:caprolactone copolymer.

As shown by Jurgens to was known to provide a bioabsorbable polymer

comprising lactide and caprolactone in a molar ration between 90:10 and 70:30.

It would have been obvious to a person having ordinary skill in the art to have provided such a bioabsorbable material to the material of Browning in view of Harvey in order to provide a polymer that is suitable for preventing surgical adhesions.

5. Claims 17 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Harvey et al. (US 5,447,940), as applied above, and further in view of Matsuda (EP 1,022,031 A1).

Browning in view of Harvey teach the claimed invention above but fail to teach that the gelatin is cross-linked and that the gelatin is subjected to a hydrophilicity imparting treatment selected from the group consisting of a plasma treatment, glow discharge treatment, corona discharge treatment, ozone treatment, graft treatment, coating, chemical treatment, and ultraviolet treatment.

Matsuda is directed to a suturable adhesion-preventing membrane with high suture strength, good biocompatibility, decomposition and absorption in a living body (Abstract). The membrane is composed of at least one non-woven fabric layer and a coating of gelatin on the surface or surfaces of the membrane (Abstract). Matsuda notes that cross-linking allows the membrane to remain in a living body while maintaining a necessary membrane strength until reconstruction of an injured surface and tissue regeneration are completed (page 6, [0043]). Matsuda teaches that the crosslinking is provided by chemical crosslinking, ultraviolet ray, thermal dehydration and other methods (page 6, [0044]). It is not seen that the specific process steps set forth in

claims distinguish the presently claimed article from the prior art articles as the references expressly suggest crosslinking the gels used therein. The courts have held that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is .unpatentable even though the prior product was made by a different process." *In re Thorpe,* 777 F.2d 695,698,227 USPQ 964,-966 (Fed. Cir. 1985).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to cross-link the gel of Browning in view of Harvey or provide a hydrophilicity imparting treatment as suggested by Matsuda motivated by the desire to create a surgical implant which is capable of remaining in the body while maintaining the necessary strength until reconstruction of the injured surface and/or tissue regeneration are completed.

6. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Harvey et al. (US 5,447,940), as applied above, and further in view of Consolazio (US 4,374,063).

Browning in view of Harvey teach the claimed invention above but fail to indicate the specific amount of endotoxin present in the gel.

Consolazio teach that the pharmaceutical field requires gels that are free from endotoxins.

It would have been obvious to a person having ordinary skill in the art to have provided an endotoxin free gel since endotoxins are bad for the body.

Response to Arguments

7. Applicant's arguments with respect to claims 1, 4 – 5, 11 – 28 and 30 - 32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CHRISS whose telephone number is (571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Chriss/
Examiner, Art Unit 1794

/J. A. C./
Examiner, Art Unit 1794